IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

ROBERT FELLNER and RENAE FELLNER, husband and wife,	)	
Plaintiffs,	)	CIVIL ACTION NO. 10-cv-00562
v.	)	Electronically Filed
MEDTRONIC, INC. and MEDTRONIC NEUROMODULATION,	)	
Defendants.	)	

DEFENDANTS' ANSWER TO PLAINTIFFS' COMPLAINT

Defendants Medtronic, Inc. and Medtronic Neuromodulation (collectively, the "Medtronic Defendants") hereby answer Plaintiffs' Complaint as follows:

1. It is admitted only that the Plaintiffs in this action are Robert Fellner and Renae Fellner. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining averments of this paragraph and therefore deny them.

2. Denied as stated. It is admitted only that Medtronic, Inc. is a corporation licensed to do business in Pennsylvania and conducts business in Pennsylvania. By way of further answer, Defendant Medtronic, Inc. has its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota.

3. Admitted.

4. Denied. By way of further answer, there is no legal entity named Medtronic Neuromodulation. Rather, that is the name for the unincorporated Neurmodulation business unit of Medtronic, Inc.

5. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

6. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them..

7. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

8. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

9. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

10. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

11. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

12. Admitted.

13. It is admitted only on information and belief that on or about November 8, 2007, Dr. Mark R. Lodico implanted a SynchroMed II Pump, Model 863740 and catheter Model 8709SC into Plaintiff Robert Fellner at the Suburban Campus of Allegheny General Hospital in Pittsburgh, Pennsylvania. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining averments in this paragraph and therefore deny them.

14. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

15. The Patient Manual is a writing that speaks for itself and Plaintiffs' characterization thereof is denied. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining averments in this paragraph and therefore deny them.

16. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

17. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

18. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

19. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

20. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

21. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

22. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

23. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

24. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

25. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

26. It is admitted only on information and belief that on April 10, 2008, Dr. Mark R. Lodico implanted a catheter Model 8709SC into Plaintiff Robert Fellner at the Suburban Campus of Allegheny General Hospital in Pittsburgh, Pennsylvania. The remaining allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

27. It is admitted only on information and belief that on April 10, 2008, Dr. Mark R. Lodico implanted a catheter Model 8709SC into Plaintiff Robert Fellner at the Suburban Campus of Allegheny General Hospital in Pittsburgh, Pennsylvania.

28. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them. The remaining allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

29. It is admitted only that on information and belief, on April 10, 2008, Dr. Mark R. Lodico implanted a catheter model 8709SC into Plaintiff Robert Fellner at the Suburban Campus of Allegheny General Hospital in Pittsburgh, Pennsylvania.

30. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

31. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

32. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

33. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

34. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

35. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

36. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

37. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

38. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

39. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

40. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

41. Denied as stated. By way of further answer, on or about June 2008, Medtronic issued a Safety Alert regarding the proper connection of sutureless connector intrathecal catheters for catheter models: 8709SC, 8731SC, 8596SC, and 8578. On September 26, 2008, the Food and Drug Administration classified the Safety Alert as a Class I recall. The Safety Alert is a writing that speaks for itself and Plaintiffs' characterization thereof is denied.

42. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

43. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

44. Denied as stated. By way of further answer, on or about August 2009, Medtronic issued a Medical Device Correction to healthcare professionals stating that sutreless connector (SC) intrathecal catheters are not compatible with IsoMed Constant-Flow Infusion Pumps. The Medical Device Correction applied to SC Catheter and Revision Kit Models: 8709SC, 8731SC, 8596SC, 8578, and IsoMed Pump Model 8472. The Medical Device Correction is a writing that speaks for itself and Plaintiffs' characterization thereof is denied.

45. Admitted.

46. Denied as stated. By way of further answer, it is admitted only that on September 14, 2009, the Food and Drug Administration classified Medtronic's Medical Device

Correction as a Class I recall. The Medical Device Correction is a writing that speaks for itself and Plaintiffs' characterization thereof is denied.

47. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

48. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

49. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them.

50. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

51. It is admitted only that Medtronic manufactured the devices implanted in Plaintiff.

52. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

53. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph and therefore deny them. The remaining allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants

specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

54. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

55. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

COUNT I

56. The Medtronic Defendants incorporate by reference the foregoing paragraphs of their Answer as if set forth fully herein.

57. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

58. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

59. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

60. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The

Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

61. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

62. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

63. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

64. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

65. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

66. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

67. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

68. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

69. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings. The Patient Manual is a writing that speaks for itself and Plaintiffs' characterization thereof is denied.

70. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

71. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

72. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

73. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

74. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

75. Denied as stated. By way of further answer, it is admitted only that Medtronic receives adverse event reports pursuant to federal law. The remaining allegations of

this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

76. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

77. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

78. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

79. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

80. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

81. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

82. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

83. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

84. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

85. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

86. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

87. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

88. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

89. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The

Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

90. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

91. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

92. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

93. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

94. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

95. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

96. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

97. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

98. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

99. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that their actions or products in any way caused injury to Plaintiff.

100. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that their actions or products in any way caused injury to Plaintiffs.

101. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that their actions or products in any way caused injury to Plaintiffs.

102. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

WHEREFORE, the Medtronic Defendants demand judgment in their favor and against Plaintiffs dismissing Count I, together with reasonable attorneys' fees and the costs of defending this action.

COUNT II

103. The Medtronic Defendants incorporate by reference the foregoing paragraphs of their Answer as if set forth fully herein.

104. It is admitted only that Medtronic manufactured the devices implanted in Plaintiff.

105. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

106. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

107. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

108. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that their actions or products in any way caused injury to Plaintiffs.

109. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

110. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that their actions or products in any way caused injury to Plaintiff.

111. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

112. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that their actions or products in any way caused injury to Plaintiff.

113. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

114. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

115. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

116. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

117. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

118. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

119. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

120. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

121. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

122. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

123. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

124. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The

Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

125. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

126. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

127. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

128. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

129. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

130. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that their actions or products in any way caused injury to Plaintiffs.

WHEREFORE, the Medtronic Defendants demand judgment in their favor and against Plaintiffs dismissing Count II, together with reasonable attorneys' fees and the costs of defending this action.

COUNT III

131. The Medtronic Defendants incorporate by reference the foregoing paragraphs of their Answer as if set forth fully herein.

132. It is admitted only that Medtronic manufactured the devices implanted in Plaintiff. The remaining allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

133. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

134. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

135. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The FDA regulations are a writing that speak for themselves and Plaintiffs' characterization thereof is denied.

136. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

137. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

138. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

139. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

140. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

141. It is admitted only that Medtronic manufactured the devices implanted in Plaintiff. The remaining allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

142. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

143. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

144. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

145. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

146. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

147. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

148. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

WHEREFORE, the Medtronic Defendants demand judgment in their favor and against Plaintiffs dismissing Count III, together with reasonable attorneys' fees and the costs of defending this action.

COUNT IV

149. The Medtronic Defendants incorporate by reference the foregoing paragraphs of their Answer as if set forth fully herein.

150. It is admitted only that Medtronic manufactured the devices implanted in Plaintiff. The remaining allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

151. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

152. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

153. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. Any implied warranties were denied by the Medtronic Defendants pursuant to UCC § 2-316 and 13 Pa. C.S. § 2316 in an express limited warranty.

154. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

155. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The

Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

156. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

157. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

158. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

159. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

160. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

161. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

162. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The

Medtronic Defendants specifically deny that their actions or products in any way caused injury to Plaintiff.

163. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that their actions or products in any way caused injury to Plaintiff.

WHEREFORE, the Medtronic Defendants demand judgment in their favor and against Plaintiffs dismissing Count IV, together with reasonable attorneys' fees and the costs of defending this action.

COUNT V

164. The Medtronic Defendants incorporate by reference the foregoing paragraphs of their Answer as if set forth fully herein.

165. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

166. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

167. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

168. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The

Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

169. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

170. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that their actions or products in any way caused injury to Plaintiff.

WHEREFORE, the Medtronic Defendants demand judgment in their favor and against Plaintiffs dismissing Count V, together with reasonable attorneys' fees and the costs of defending this action.

COUNT VI

171. The Medtronic Defendants incorporate by reference the foregoing paragraphs of their Answer as if set forth fully herein.

172. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

173. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The

Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

174. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

175. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

WHEREFORE, the Medtronic Defendants demand judgment in their favor and against Plaintiffs dismissing Count VI, together with reasonable attorneys' fees and the costs of defending this action.

COUNT VII

176. The Medtronic Defendants incorporate by reference the foregoing paragraphs of their Answer as if set forth fully herein.

177. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that the Model 8709SC catheter implanted in Plaintiff was defective or accompanied by inadequate warnings.

178. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

179. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

180. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

181. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

182. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that their actions or products in any way caused injury to Plaintiff.

183. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied.

WHEREFORE, the Medtronic Defendants demand judgment in their favor and against Plaintiffs dismissing Count VII, together with reasonable attorneys' fees and the costs of defending this action.

COUNT VIII

184. The Medtronic Defendants incorporate by reference the foregoing paragraphs of their Answer as if set forth fully herein.

185. The Medtronic Defendants lack knowledge or information sufficient to form a belief as to the truth of the averment in this paragraph and therefore deny it.

186. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The Medtronic Defendants specifically deny that their actions or products in any way caused injury to Plaintiffs.

187. The allegations of this paragraph state legal conclusions to which no response is required. To the extent that a response is required, the allegations are denied. The

Medtronic Defendants specifically deny that their actions or products in any way caused injury to Plaintiffs.

WHEREFORE, the Medtronic Defendants demand judgment in their favor and against Plaintiffs dismissing Count VIII, together with reasonable attorneys' fees and the costs of defending this action.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails to state cognizable claims against the Medtronic Defendants upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the applicable statute of limitations and/or the doctrine of laches.

THIRD AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries are unrelated to the alleged use of the Medtronic Defendants' products and resulted from acts, occurrences, conditions, products or equipment for which the Medtronic Defendants are not liable or responsible.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries at issue in this Complaint were not proximately caused by a product of the Medtronic Defendants, or by any conduct of the Medtronic Defendants.

FIFTH AFFIRMATIVE DEFENSE

The product at issue in the Complaint may be dispensed and used only under prescription of a physician. The user of the product is therefore not Plaintiff, but a learned intermediary, that is, Plaintiff's physician, and no warning was required to be given by the Medtronic Defendants to Plaintiff under Pennsylvania law.

SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by the common law doctrine of comparative negligence, in that the negligence of Plaintiffs Robert Fellner and Renae Fellner was greater than that of the Medtronic Defendants. In the alternative, Plaintiffs' claims are limited by the common law of comparative negligence to the extent of the Plaintiffs' negligence.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, to the extent that the alleged injuries, if any, were caused by the misuse or abuse by Plaintiffs and/or other persons of the product at issue in this Complaint.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Plaintiff assumed the risk of their injuries, if any, and of their activities.

NINTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, to the extent that the product at issue underwent substantial change after it left the control of the Medtronic Defendants, and before Plaintiffs sustained their alleged injuries.

TENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, to the extent that Plaintiffs' injuries, if any, were caused by the alteration and/or method of implantation and/or maintenance and/or use of the product at issue in the Complaint, or by other causes which occurred after the product left the control of Medtronic.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs failed to give Medtronic timely notice of any alleged breach of warranty (the existence of all implied warranties being expressly denied) and such claims are therefore barred.

TWELFTH AFFIRMATIVE DEFENSE

All implied warranties were properly excluded and remedies limited by Medtronic pursuant to U.C.C. § 2-316 and 13 Pa. C.S. § 2316.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are preempted by the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321-394 (1998 and Supp. III 1991) because the products at issue received premarket approval by the Food and Drug Administration.

FOURTEENTH AFFIRMATIVE DEFENSE

The product at issue is an "unavoidably unsafe" product under Comment k to Section 402 of the Restatement (Second) of Torts and was properly prepared and accompanied by proper directions and warnings.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, to the extent that Plaintiffs' injuries were caused by the failure to prepare or use the device in compliance with the instructions, labels and warnings provided by the Medtronic Defendants.

SIXTEENTH AFFIRMATIVE DEFENSE

The Medtronic Defendants expressly reserve the right to assert any additional affirmative defenses that may be revealed during the course of discovery.

DATED: May 10, 2010

Respectfully submitted,

s/ John P. Lavelle, Jr.
John P. Lavelle, Jr., PA54279
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103
(215) 963-4824
(215) 963-5001 (Facsimile)
jlavelle@morganlewis.com

Attorney for Defendants

CERTIFICATE OF SERVICE

I hereby certify that on May 10, 2010, the foregoing Defendants' Answer to Plaintiffs' Complaint was served upon the following via Electronic Court Filing System:

Daniel W. Ernsberger
Behrend & Ernsberger, P.C.
Park Building – 12th Floor
355 Fifth Avenue
Pittsburgh, PA 15222

Attorney for Plaintiffs

s/ John P. Lavelle, Jr.
John P. Lavelle, Jr.